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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,333	09/29/2005	Kenji Motokawa	082368-002100US	2713

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,333	MOTOKAWA ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,11 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5, 11 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summery

The amendment and response submitted on Nov. 11, 2009 have been noted. Claims 1 and 3 have been amended. Claims 2, 4, 6-10 and 12 have been canceled. New claim 13 has been added. Claims 1, 3, 5, 11 and 13 are pending and considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 5 are still rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Applicants traverse the rejection and submit that claim 1 has been amended to define the variant thereof having an immunological activity for stimulating immunocompetent cells; therefore, the rejection should be withdrawn in view of the explanation of specification in pages 13 and 15 for the general methods of epitope determination and cellular immunity of CTL test.

4. Applicants' argument has been respectfully considered; it is not found persuasive. According to the new guideline of written description, especially, the claimed subject matter is directed to a genus of polypeptides that read on astronomic numbers of polypeptide variants of SEQ ID NO: 2. Applicants in the specification only disclose and teach one polypeptide of SEQ ID NO: 2 used for inducing a neutralizing antibody. No any other species of variants as claim drafted is disclosed.

5. The new guidelines for determining whether Applicants have a possession for the claimed subject or the claimed subject matter lacks of a written description set forth below:

6. 1). Full coverage of the claimed scope of invention; 2). Whether applicant provides sufficient support to support the full scope of the invention and 3). Whether one skilled in the art

would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing according to the disclosure of the entire application. This should include the following aspects of the considerations:

a. Actual reduction to practice;

b. Disclosure of drawings or structural chemical formulas;

c. Sufficient relevant identifying characteristics including i). Complete structure, ii). Partial structure; iii). Physical and/or chemical properties and iv). Functional characteristics when coupled with a known or disclosed correlation between function and structure;

d. Method of making the claimed invention;

e. Level of skill and knowledge in the art; and

f. f. Predictability in the art.

7. In the instant case, no reduction of practice has been shown for any other species of the claimed polypeptides variants; the specification also lacks of description of structure and function relationship regarding which amino acid position(s) in the lengthy 377 amino acids should be mutated and how to mutated. While the methods for determining an immunogenic epitope or a cellular immune response assay are routine techniques, the enablement and written description are two separate issues. For example, while a specification contains some information for producing a variant, but it makes no reference to the real variant in question.

8. MPEP § 2163.02 states, "[a] n objective standard for determining compliance with the written description requirement is "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Especially, the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. Because factual evidence of an actual reduction to practice has not been disclosed by Applicant in the

specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; absent a detail description of representative numbers of the claimed genus of polypeptide of SEQ ID NO: 2 variants, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of polypeptide variants. The full breadth of the claims does not meet the written description and enablement provision of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3, 5, 11 and 13 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Wasmoen et al. (US Patent 5,770,211) in view of Motokawa et al. (Microbiology and Immunology, 1996, Vol. 40, No. 6, pages 425-433) and Duphar International Research (EP 0 411 684 A2, 1991), which is further substantiated by Wasmoen et al. (B) (Adv. Exp. Biol. 1995, Vol. 380, pp. 221-228).

11. It is noted that the rejection is still based on one of scope of claims read on using the polypeptide of SEQ ID NO: 2 that was known prior to the current Application was filed.

12. Applicants transverse the rejection in the response and submit that prior to the current Application was filed (1992), and six year after the Wasmen reference cited above, most FIPV vaccine using N protein of type I Feline infectious peritonitis (FIP) were largely unsuccessful as evidenced by German et al. by using S protein.

13. Moreover, Applicants submitted that the expert Horzinek in the field indicates that 75% of immunized cats got protective cellular immune responses by immunization with the N protein of the type I FIPV, although the neutralizing activity is not observed.

14. This argument is not persuasive, because the claimed subject matter is to use N protein to induce a protective immune response rather then using S protein. Moreover, the claimed subject matter is not directed to any particular type of immune response. The mechanism for a claimed method or product does not add any patentable weight in turn of structure of the claimed subject matter and the function inherently thereto.

15. In contrast to Applicants assertion that using N protein to immune cat is unpredictable, it is noted that prior to the current application was filed, Wasmoen et al. in (B) also teach that immunizing cats with N protein of an IFPV strain can successfully induce a protective immune response when it is used as a DNA vaccine (Wasmoen et al. (B) see Table 2 & 4, Fig. 1). This disclosure by Wasmoen et all in (A) and (B) are motivation for any person ordinarily skilled in the art to use the polypeptide of N protein available in the art for making and using it as an immunogenic composition to immunize cats against FIPV infection with expected success, since the DNA encoding N protein immunization was already approved to be successful.

16. Therefore, absence of the evidence to show that only N protein of SEQ ID NO: 2 can produce a protective immune response, whereas the N proteins from other FIPV strain can not, the claimed subject matter as a whole is still considered prima facie obvious absence unexpected results. The rejection is maintained.

17. New ground of rejection:

Claim Rejections - 35 USC § 112

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1, 3, 5, 11 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using an immunogenic composition comprising the N protein from type II IFPV set forth in SEQ ID NO: 2 and adjuvant L80 and aluminum hydroxide to induce a protective immune response after repeated three times of immunizations in cats, does not reasonably provide enablement for having a vaccine to induce a protective immune response with any polypeptide having upon to 15 amino acid residues random mutations in SEQ ID NO: 2

or 95% homology to the SEQ ID NO: 2 or 45 consecutive amino acid residues of SEQ ID NO: 2, especially with less then three time of immunization. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

20. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art with undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is one or more following factors in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). 1). Nature of invention, 2). Scope of claim encompassed, 3). State of art and Unpredictability of the field at the time of invention was filed, 4). Working example taught by the specification; 5).Guidance provided by the specification, 6). Level of skill in the art, and 7). Amount of work need to fulfill the scope of claims encompassed.

21. The nature of invention is a method of immunizing cat from FIPV infection by using N protein of type II IFPV set forth in SEQ ID NO: 2 in an immunogenic composition with three boosting immunization protocol to obtain a protective immune response. The scope of claims is broadly drawn to vaccine and method using the same, wherein the vaccine comprises a variant of a N protein having a mutation with 1-15 or 19 (95% of 377 amino acids) amino acids random mutations within SEQ ID NO: 2 or 45 consecutive amino acid residues of SEQ ID NO: 2. The method is also directed to use the composition less than 3 times of boost immunization.

22. The state of art teaches that a protective immune response against FIPV is unpredictable because the neutralizing antibody can not protect the infection and it also induces an antibody-depended enhancement of infection (ADE). One of mechanism is attribute which class of an antibody is induced by a FIPV viral antigen. It is very unpredictable what kind of humoral immune response would be induced by so many undefined random mutations of SEQ ID NO: 2 variants, because it is well known in the art that a single amino acid mutation can change the biological activity of a protein or the property of an antigen as evidenced by Betti et al. who teach that a Tat mutant with only two amino acid mutations lacks tat-transactivating activity (Vaccine 2001, Vol. 19, no. 25-26, pp. 3408-3419, please see pages 3408 and 3412-3413), Mellins et al. (J. Exp. Med. 1988, Vol. 168, pp. 1531-1537), who teach that a single amino acid

change alters antigen presentation class in the antigen presenting cell and Song et al. (Molecular Biology of the Cell 2004, Vol. 15, pp. 1287-1296), who teach that a single amino acid change in a protein "surviving converse the protein from anti-apoptotic to pro-apoptotic.

23. Applicants do not provide adequate guidance and any working example regarding which 1-15 or 1-19 amino acid residues among the 377 amino acids should be changed and how to change it. In view of astronomic numbers of variants of SEQ ID NO: 2 as claim 1 drafted, and there is not any single species of such variants disclosed, it is concluded that the specification is not sufficient to support the broadly scope of claims encompassed.

24. Moreover, the level of skill for making so many astronomic numbers of changes with an expected protective immune response is very high at the phD level of molecular biology and virology. Without sufficient guidance, a person skill in the art would have to do undue experimentation to fulfill the scope of claims encompassed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mondesi Robert can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Examiner, Art Unit 1648